### **REMARKS**

Applicant has amended claims 22, 26, 37, and 49 solely to correct typographical errors.

Upon entry of this Amendment, claims 1-54 remain pending and under current examination.

## **Regarding the Office Action:**

In the Office Action, the Examiner objected to the Information Disclosure Statement filed on March 8, 2004; objected to claims 26, 37, and 49 for informalities; rejected claims 22, 24-45, and 48-54 under 35 U.S.C. § 112, 2nd paragraph; rejected claims 23 and 45 under 35 U.S.C. § 101; rejected claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42, and 44 under 35 U.S.C. § 102(b) as being anticipated by Cohen (U.S. Patent No. 5,174,289) ("Cohen"); rejected claim 3 under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Cohen; rejected claims 27, 33, and 43 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Helland (U.S. Patent No. 5,385,579) ("Helland"); rejected claims 13, 14, 17, 36, 37, and 40 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Prystowsky et al. (U.S. Patent No. 4,554,922) ("Prystowsky"); rejected claims 15 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Prystowsky as applied to claim 13, and further in view of Altman (U.S. Patent No. 5,551,427) ("Altman"); rejected claim 28 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Smits (U.S. Patent No. 4,641,656) ("Smits"); rejected claims 34, 38, 39, 45-47, 51, and 52 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Smits and further in view of Altman; and rejected claims 48-50, 53, and 54 under 35 U.S.C. § 103(a) as being unpatentable over Cohen in view of Smits, Altman, and Prystowsky. Applicant traverses the objections and rejections for the following reasons.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> The Office Action may contain statements characterizing the related art, case law, and claims. Regardless of whether any such statements are specifically identified herein, Applicant declines to automatically subscribe to any statements in the Office Action.

### **Objection to the Drawings:**

The Office Action Summary Sheet (PTOL-326) indicates that the drawings were objected to, yet the Office Action contained no text regarding the objection. Applicant deems the drawings in full compliance with the pertinent statutes and regulations. If the Examiner intended to object to the drawings, Applicant requests the Examiner detail the objection to afford Applicant the opportunity to reply.

## **Objection to the Information Disclosure Statement:**

The Examiner objected to the Information Disclosure Statement (IDS) "because several of the documents are missing publication dates and several of the documents less than one year old are lacking publication months" (Office Action, p. 2). Applicant is submitting a Supplemental IDS along with this Amendment, to properly cite the documents cited in the March 8, 2004, IDS, and to cite additional documents. Applicant requests an initialed PTO/SB/08 form in the next communication from the Office, indicating the Examiner's consideration of all listed documents.

#### Objection to Claims 26, 37, and 49:

The Examiner objected to claims 26, 37, and 49 for informalities, and required appropriate correction. In response, Applicant has amended claims 26, 37, and 49 to correct the typographical errors the Examiner pointed out. Applicant therefore deems the objection overcome.

## Rejection of Claims 22, 24-45, and 48-54 under 35 U.S.C. § 112, 2nd Paragraph:

First, Applicant has amended claim 22 to correct the inadvertent antecedent basis error by deleting the word "the." Applicant therefore deems the rejection of claim 22 overcome.

Second, the Examiner alleged that claims 24-45 and 48-54 are

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims specify stimulating the heart from locations 'in the left ventricle'. Applicant discloses that 'installing a similar lead into the left ventricle may create a danger to the patient due to the possibility of a thrombus being generated', and further discloses an exemplary embodiment in Fig. 4 in which the leads are placed around or on the left ventricle. It is unclear whether applicant is claiming electrodes placed in the ventricle, on the ventricle, or both. Examiner is interpreting the claims to be directed to electrodes placed on the ventricles, as is customary in the art, and as claimed in claim 52. (Office Action, p. 4).

In response, Applicant notes that "[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. [...] Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification."

M.P.E.P. § 2173.05(b), 8th Ed., Rev. 4 (October 2005), p. 2100-216. One of ordinary skill in the art would readily understand what Applicant has claimed, in light of the specification.

The Examiner has <u>incorrectly</u> read Applicant's specification and independent claims 24, 41, 48, and 51, which call for "stimulating the left ventricle of the heart at a plurality of locations <u>in</u> the left ventricle" (claim 24, emphasis added), "stimulating contraction at a plurality of locations <u>in</u> the left ventricle" (claim 41, emphasis added), "stimulate contraction to at least a second electrode implanted <u>in</u> the left ventricle" (claim 48, emphasis added), and "applying a second electrical signal to a second electrode implanted <u>in</u> the left ventricle" (claim 51, emphasis added).

As the Examiner pointed out, Applicant discloses that "[w]hile it is relatively safe to insert a pacing lead and associated electrode(s) into the right ventricle, installing a similar lead into the left ventricle may create a danger to the patient due to the possibility of a thrombus being generated which might result in an ischemic episode" (par. [0058]). However, the Examiner has overlooked the two sentences *immediately following* the above-quoted sentence, where Applicant

discloses that "[i]t is therefore important to implant the leads in the left ventricle <u>using a safe</u> <u>method</u>. Fig. 4 illustrates two pacing electrodes 402 and 404 that are designed to be implanted <u>in</u> the left ventricle <u>in a safe manner</u>" (*Id.*, emphasis added). This is further demonstrated by the illustration provided in Fig. 4, showing electrode 404 implanted <u>in</u> the left ventricle. Thus, the Examiner's allegation that Applicant "discloses an exemplary embodiment in Fig. 4 in which the leads are placed <u>around or on the left ventricle</u>" (Office Action, p. 4, emphasis added), <u>cannot be</u> true.

Further, dependent claim 52 calls for the second electrode to be "implanted in one of the coronary sinus, a coronary vein the left ventricle, the interventricular septum, or in an epicardial wall of the left ventricle." This adds further limitations to independent claim 51, which is to be construed as broadly as possible, consistent with the disclosure. Thus, it is improper for the Examiner to limit any of independent claims 24, 41, 48, and 51 to only the specific elements recited in dependent claim 52. That is, it is improper for the Examiner to limit the claimed invention by "interpreting the claims to be directed to electrodes placed on the ventricles, as is customary in the art, and as claimed in claim 52" (Office Action, p. 4). The relative inquiry is to the application as a whole, including the independent claims, and is not "as is customary in the art" or "as claimed in claim 52."

The M.P.E.P. sets forth that the "[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) [t]he content of the particular application disclosure; (B) [t]he teachings of the prior art; and (C) [t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

See M.P.E.P. § 2173.02, p. 2100-213. A full examination of the contents of the disclosure, particularly Applicant's entire par. [0058], Fig. 4, and the language of independent claims 24, 41,

48, and 51, indicates that the claims meet the definiteness requirement requirements of 35 U.S.C. § 112, 2nd paragraph. Thus, the Examiner's allegation that "[i]t is unclear whether applicant is claiming electrodes placed in the ventricle, on the ventricle, or both" (Office Action, p. 4), is baseless and without merit.

The reasoning presented above overcomes the 35 U.S.C. § 112, 2nd paragraph, rejection. Accordingly, Applicant requests withdrawal of the rejection of claims 22, 24-45, and 48-54, and an indication that they are now allowed.

### Rejection of Claims 23 and 45 under 35 U.S.C. § 101:

The Examiner alleged "the claimed invention is directed to non-statutory subject matter. These claims comprise electrodes implanted in the heart. This implies that the invention comprises a portion of the human anatomy, which is non-statutory subject matter" (Office Action, pp. 4-5). The Examiner's position is based on an inaccurate interpretation of U.S. patent law.

The U.S. Supreme Court has stated that Congress intended statutory subject matter to "include anything under the sun that is made by man." *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *see also* M.P.E.P. § 2105, 8th Ed., Rev. 4 (October 2005), p. 2100-3, citing S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952). The Supreme Court, however, also noted three exceptions that constitute the following categories of unpatentable subject matter: "laws of nature, natural phenomena, and abstract ideas." *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

According to the Federal Circuit, the inquiry of whether a claim is statutory focuses on "the essential characteristics of the subject matter, in particular, its practical utility." See State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir.

1998). If a claim includes recitations that produce "a concrete, tangible and useful result," the claim is not abstract and has practical utility. *Id.* at 1373; *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1358 (Fed. Circ. 1999); *see also* M.P.E.P. § 2106. Thus, if the claim is not abstract and has practical utility, it is statutory under 35 U.S.C. § 101.

Claims 23 and 45 both call for "[a] system for controlling contraction of a heart," further comprising "a plurality of electrodes, wherein at least two of the plurality of electrodes are implanted in a single chamber of the heart" (claim 23), and "a first electrode implanted in the interventricular septum; and a second electrode implanted in a coronary vein of the left ventricle" (claim 45). It is clear that claims 23 and 45 produce a concrete, tangible, and useful result, and are thus statutory.

The Examiner alleged that the rejected claims are not statutory because the claim language "implies that the invention comprises a portion of the human anatomy" (Office Action, p. 4). This is an inaccurate interpretation of U.S. patent law. M.P.E.P. § 2105 explains that

[i]t is clear from the Supreme Court decision [in *Chakrabarty*, citations omitted] and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention. M.P.E.P. § 2105, p. 2100-3, emphasis added.

The subject matter of claims 23 and 45 satisfies the tests of *Chakrabarty*, as laid out in the M.P.E.P., specifically that "(B) A 'nonnaturally occurring manufacture or composition of matter - a product of human ingenuity - having a distinctive name, character, [and] use' is patentable subject matter, and "(D) '[T]he production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties, or combinations whether by hand labor or by machinery*' [emphasis added] is a 'manufacture' under 35 U.S.C. 101."

M.P.E.P. § 2105, p. 2100-4. Thus, "'a nonnaturally occurring manufacture or composition of matter' is patentable." *Id*.

Moreover, the Examiner's allegation also appears to be based on an incorrect reading of M.P.E.P. § 2105, which states that "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter." M.P.E.P. § 2105, p. 2100-5. It is clear, however, that Applicant's claims 23 and 45, as a whole, do not encompass a human being. Rather, claims 23 and 45 call for "a system for controlling contraction of a heart" with an electrode or electrodes. Therefore, the Examiner's allegation that "[t]his implies that the invention comprises a portion of the human anatomy, which is non-statutory subject matter" (Office Action, pp. 4-5), is baseless and without merit.

The reasoning presented above overcomes the 35 U.S.C. § 101 rejection. Accordingly, the improper 35 U.S.C. § 101 rejection of claims 23 and 45 should be withdrawn.

<u>Rejection of Claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42, and 44 under 35 U.S.C.</u> § 102(b):

Applicant traverses the rejection of claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42, and 44 under 35 U.S.C. § 102(b) as being anticipated by <u>Cohen</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions.

In order to properly establish that <u>Cohen</u> anticipates Applicant's claimed invention under 35 U.S.C. § 102, each and every element of each of the claims in issue must be found, either expressly described or under principles of inherency, in that single reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *See* M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9

U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). <u>Cohen</u> does not disclose each and every element of Applicant's claimed invention.

First, Cohen does not disclose at least Applicant's claimed "stimulating a chamber of the heart at a plurality of locations in the chamber based on the progress of contraction" (independent claim 1). Rather, an examination of Cohen's claim 1 (cited by the Examiner) reveals that Cohen discloses "(e) providing pacing pulses from said pulse generator to at least two selected terminals, one at a time, at a constant rate determined to stimulate said ventricular muscle," "(g) setting said implantable pulse generator at a desired predetermined time interval," and "employing the first of said cardiac signal [...] within said predetermined time interval and caus[ing] the deliverance of pacing pulses to said selected terminal upon the absence of any said cardiac signal with said predetermined time interval" (Cohen, claim 1, emphasis added). This clearly does not constitute Applicant's claimed "stimulating a chamber of the heart at a plurality of locations in the chamber based on the progress of contraction" (claim 1, emphasis added). Thus, Cohen does not anticipate Applicant's claim 1.

Second, the Examiner does not include any mention of independent claim 18 in the body of the rejection. The Examiner does not demonstrate that <u>Cohen</u> anticipates claim 18, and the rejection of claim 18 is improper for at least this reason. Nevertheless, Applicant points out that the rejection is also improper because <u>Cohen</u> does not disclose Applicant's claimed "means for stimulating a chamber of the heart at a plurality of locations in the chamber *based on the progress of contraction*" (claim 18, emphasis added), for the reasons presented in the previous paragraph. Thus, <u>Cohen</u> does not anticipate Applicant's claim 18.

Third, <u>Cohen</u> does not disclose at least Applicant's claimed "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24). Rather,

Cohen stimulates the septum along the side of the *right* ventricle wall. *See* Cohen's Figs. 8C and 10C, for example. Applicant points out that the star-shaped dots on the left ventricle side of the heart diagram in Cohen's Figs. 8C, 9, 10C, and 11 are not electrodes. Rather, they indicate the "last cells to fire," at 65 and 78 msec, respectively, in response to the stimulation from the pacing lead in the *right* ventricle. This clearly does not constitute Applicant's claimed "stimulating the left ventricle of the heart *at a plurality of locations in the left ventricle*" (claim 24, emphasis added). Thus, Cohen does not anticipate Applicant's claim 24.

Fourth, <u>Cohen</u> does not disclose at least Applicant's claimed "a signal generator, coupled to the processor, to provide at least one electrical signal for selectively stimulating contraction at a plurality of locations in the left ventricle in response to the one or more control signals" (independent claim 41). Again, Applicant points out that <u>Cohen</u> stimulates the septum along the side of the *right* ventricle wall. *See* <u>Cohen</u>'s Figs. 8C and 10C, for example, and the reasoning presented in the previous paragraph. This clearly does not constitute Applicant's claimed "stimulating contraction at a plurality of locations in the left ventricle in response to the one or more control signals" (claim 41, emphasis added). Thus, <u>Cohen</u> does not anticipate Applicant's claim 41.

Thus, <u>Cohen</u> does not anticipate any of Applicant's independent claims 1, 18, 19, 24, and 41. Independent claims 1, 18, 19, 24, and 41 are therefore allowable, and dependent claims 2, 4-12, 20-23, 25, 26, 29-32, 35, 42, and 44 are also allowable at least by virtue of their respective dependence from allowable base claim 1, 18, 19, 24, or 41. Therefore, the improper 35 U.S.C. § 102(b) rejection of claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42, and 44 should be withdrawn.

# Rejection of Claim 3 under 35 U.S.C. § 102(b) / 35 U.S.C. § 103(a):

Applicant traverses the rejection of claim 3 as being anticipated by, or unpatentable over, Cohen. Applicant respectfully disagrees with the Examiner's arguments and conclusions.

(1) Applicant challenges the Examiner's 35 U.S.C. § 102/103 combination rejection as improper and without merit, even before addressing the deficiencies of <u>Cohen</u>. Applicant directs the Examiner to M.P.E.P. § 706.02(IV), which states:

The distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. Whereas, in a rejection based on 35 U.S.C. 103, the reference teachings must somehow be modified in order to meet the claims. The modification must be one which would have been obvious to one of ordinary skill in the art at the time the invention was made. M.P.E.P. § 706.02(IV), p. 700-23.

The M.P.E.P. clearly instructs that, for a proper 35 U.S.C. § 102 rejection, "[n]o question of obviousness is present." *Id.* Therefore, if the Examiner applies a 35 U.S.C. § 102(b) rejection of Applicant's claim 3 based on <u>Cohen</u>, this must necessarily preclude a 35 U.S.C. § 103(a) rejection of the same claim, based on the same reference, for the same reason.

Similarly, the M.P.E.P. clearly instructs that, for a proper 35 U.S.C. § 103 rejection, "the reference teachings must somehow be modified in order to meet the claims." *Id.* Therefore, if the Examiner applies a 35 U.S.C. § 103(a) rejection of Applicant's claim 3 based on <u>Cohen</u>, this must necessarily preclude a 35 U.S.C. § 102(b) rejection of the same claim, based on the same reference, for the same reason.

Thus, if the Examiner alleges that <u>Cohen</u> meets all the claim limitations of rejected claim 3 in a 35 U.S.C. § 102(b) rejection, then he cannot also apply a 35 U.S.C. § 103(a) rejection of the same claim -- in combination with the 35 U.S.C. § 102(b) rejection, for this necessarily

admits the impropriety of the 35 U.S.C. § 102(b) rejection. Likewise, if the Examiner alleges that Applicant's claim 3 is obvious in a 35 U.S.C. § 103(a) rejection, then he cannot also apply a 35 U.S.C. § 102(b) rejection in combination with the 35 U.S.C. § 103(a) rejection, for this necessarily admits the impropriety of the 35 U.S.C. § 103(a) rejection. This is in part because a proper 35 U.S.C. § 103(a) rejection requires that "the reference teachings must somehow be *modified* in order to meet the claims." *Id.*, emphasis added

Moreover, "[i]t is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply." M.P.E.P. § 706.02(j). The Examiner's rejection is not properly communicated in a manner affording Applicant a fair opportunity to reply, for the reasons outlined in the previous paragraph. For example, assuming the Examiner only applied a 35 U.S.C. § 103(a) rejection of claim 3, the M.P.E.P. instructs that,

"[a]fter indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
  - (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification." Id.

For the purposes of a 35 U.S.C. § 103(a) rejection, the Examiner has not set forth "the difference or differences in the claim over the applied reference(s)," or "an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification." *Id*.

Instead, in reference to the 35 U.S.C. § 103(a) rejection, the Examiner said "Cohen discloses that his invention can be applied to the atrial chambers as well as the ventricular chambers" (Office Action, p. 7). This does not explain the difference or differences in the claim over the applied reference. Further, the Examiner alleged that "it would have been obvious ... to modify Cohen's invention by sensing from multiple locations in the atrium..." (Office Action, p. 7). This does not explain why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

Therefore, the Examiner's alleged 35 U.S.C. § 102/103 combination rejection is wholly improper on its face, before addressing the deficiencies in the cited reference. If the Examiner's 35 U.S.C. § 102(b) rejection is supposedly valid in the context of this rejection, the 35 U.S.C. § 103(a) rejection is necessarily improper; and if the 35 U.S.C. § 103(a) rejection is supposedly valid, the 35 U.S.C. § 102(b) is necessarily improper.

Nevertheless, in order to respond to the Office Action in as complete a manner as possible under these circumstances, Applicant respectfully traverses the Examiner's rejection, as detailed above, for the following additional reasons.

- (2) Applicant traverses the 35 U.S.C. § 102(b) portion of the rejection of claim 3 over Cohen. Dependent claim 3 includes everything recited in base claim 1. See M.P.E.P. § 608.01(n)(III), p. 600-88. Applicant has established, in the previous section, that Cohen does not anticipate claim 1. Therefore, dependent claim 3 is also allowable at least by virtue of its dependence from allowable base claim 1. Therefore, the improper 35 U.S.C. § 102(b) portion of the rejection of claim 3 should be withdrawn.
- (3) Applicant traverses the 35 U.S.C. § 103(a) portion of the rejection of claim 3 over Cohen. Notwithstanding the fact that the 35 U.S.C. § 103(a) rejection fails for the reasons set

forth in "(1)" above, Applicant notes that the discussion in "(2)," regarding the 35 U.S.C. § 102(b) portion of the rejection, demonstrates that <u>Cohen</u> does not teach or suggest each and every element of independent claim 1. Therefore, the Examiner has not met an essential criterion for establishing a *prima facie* case of obviousness, wherein "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *See* M.P.E.P. §§ 2142, 2143, and 2143.03. Since establishing a *prima facie* case of obviousness requires that the cited reference or references teach or suggest each and every element of the claimed invention, the Examiner's 35 U.S.C. § 103(a) rejection fails on at least this point.

Therefore, the Examiner's reliance on <u>Cohen</u> fails to establish *prima facie* obviousness. Independent claim 1 is therefore allowable, for the reasons argued above, and dependent claim 3 is also allowable at least by virtue of its dependence from allowable base claim 1. Therefore, the improper 35 U.S.C. § 103(a) portion of the rejection of claim 3 should be withdrawn.

# Rejection of Claims 27, 33, and 43 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claims 27, 33, and 43 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Helland</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). M.P.E.P. § 2142, 8th Ed., Rev. 4 (October 2005), p. 2100-134.

A *prima facie* case of obviousness has not been established because, among other things, neither <u>Cohen</u> nor <u>Helland</u>, nor their combination, teaches or suggests each and every element of Applicant's claims. Specifically, the first requirement for establishing a *prima facie* case of obviousness has not been established, because <u>Cohen</u> and <u>Helland</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claims 24 and 41, from which claims 27, 33, and 43 respectively depend.

Applicant has already demonstrated previously herein that <u>Cohen</u> does not teach or suggest all the elements of independent claims 24 and 41. In addition, the Examiner admitted that <u>Cohen</u> does not teach "providing epicardial electrodes implanted in the epicardial wall" (Office Action, p. 7).

The Examiner's application of <u>Helland</u>, however, for its "epicardial electrodes implanted in the epicardial wall" (Office Action, p. 7), fails to cure the deficiencies of <u>Cohen</u> already discussed. That is, <u>Helland</u> also fails to teach or suggest at least the claimed "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24), and the claimed "a signal generator, coupled to the processor, to provide at least one electrical signal for selectively stimulating contraction at a plurality of locations in the left ventricle in response to the one or more control signals" (independent claim 41).

Thus, even if <u>Helland</u> were combined with <u>Cohen</u> as the Examiner suggests, <u>Cohen</u> and <u>Helland</u> do not teach or suggest all elements recited in independent claims 24 and 41, and required by dependent claims 27, 33, and 43. Therefore, the Examiner's application of <u>Helland</u> as an additional reference does not render obvious the recitations of Applicant's dependent claims 27, 33, and 43.

For at least these reasons, the Examiner's rejection is improper and without merit. Accordingly, the Examiner's reliance on <u>Cohen</u> and <u>Helland</u> fails to establish *prima facie* obviousness of dependent claims 27, 33, and 43. Dependent claims 27, 33, and 43 are also allowable at least by virtue of their respective dependence from allowable base claim 24 or 41. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### Rejection of Claims 13, 14, 17, 36, 37, and 40 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claims 13, 14, 17, 36, 37, and 40 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Prystowsky</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

A *prima facie* case of obviousness has not been established because, among other things, neither <u>Cohen</u> nor <u>Prystowsky</u>, nor their combination, teaches or suggests each and every element of Applicant's claims. Specifically, <u>Cohen</u> and <u>Prystowsky</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claims 1 and 24, from which claims 13, 14, 17, 36, 37, and 40 respectively depend.

Applicant has already demonstrated previously herein that <u>Cohen</u> does not teach or suggest all the elements of independent claims 1 and 24. In addition, the Examiner admitted that <u>Cohen</u> does not teach "applying either an anodal or cathodal sub-threshold pre-excitation voltage with a current of about 10 mA" (Office Action, p. 7).

The Examiner's application of <u>Prystowsky</u>, however, for its "sub-threshold pre-excitation voltage of about 10 mA (col. 5, line 48) to inhibit arrhythmic beats" (Office Action, p. 7), fails to cure the deficiencies of <u>Cohen</u> already discussed. That is, <u>Prystowsky</u> also fails to teach or suggest at least the claimed "stimulating a chamber of the heart at a plurality of locations in the

 $\gamma = \beta - J_{i}$ 

chamber based on the progress of contraction" (independent claim 1), and "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24).

Thus, even if <u>Prystowsky</u> were combined with <u>Cohen</u> as the Examiner suggests, <u>Cohen</u> and <u>Prystowsky</u> do not teach or suggest all elements recited in independent claims 1 and 24, and required by dependent claims 13, 14, 17, 36, 37, and 40. Therefore, the Examiner's application of <u>Prystowsky</u> as an additional reference does not render obvious the recitations of Applicant's dependent claims 13, 14, 17, 36, 37, and 40.

For at least these reasons, the Examiner's rejection is improper and without merit. Accordingly, the Examiner's reliance on Cohen and Prystowsky fails to establish *prima facie* obviousness of dependent claims 13, 14, 17, 36, 37, and 40. Dependent claims 13, 14, 17, 36, 37, and 40 are also allowable at least by virtue of their respective dependence from allowable base claim 1 or 24. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### Rejection of Claims 15 and 16 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Prystowsky</u>, as applied to claim 13, and further in view of <u>Altman</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

A *prima facie* case of obviousness has not been established because, among other things, none of <u>Cohen</u>, <u>Prystowsky</u>, <u>Altman</u>, or their combination, teaches or suggests each and every element of Applicant's claims. Specifically, <u>Cohen</u>, <u>Prystowsky</u>, and <u>Altman</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claim 1, from which claims 15 and 16 depend.

Applicant has already demonstrated in the previous section that <u>Cohen</u> and <u>Prystowsky</u> do not teach or suggest all the elements of independent claim 1. In addition, the Examiner admitted that <u>Cohen</u> and <u>Prystowsky</u> do not teach "an electrode implanted in the interventricular septum" (Office Action, p. 8).

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The Examiner's application of <u>Altman</u>, however, for its "septal electrode using a helical wire" (Office Action, p. 8), fails to cure the deficiencies of <u>Cohen</u> and <u>Prystowsky</u> already discussed. That is, <u>Altman</u> also fails to teach or suggest at least the claimed "stimulating a chamber of the heart at a plurality of locations in the chamber based on the progress of contraction" (independent claim 1).

Thus, even if <u>Altman</u> were combined with <u>Cohen</u> and <u>Prystowsky</u> as the Examiner suggests, <u>Cohen</u>, <u>Prystowsky</u>, and <u>Altman</u> do not teach or suggest all elements recited in independent claim 1, and required by dependent claims 15 and 16. Therefore, the Examiner's application of <u>Altman</u> as an additional reference does not render obvious the recitations of Applicant's dependent claims 15 and 16.

For at least these reasons, the Examiner's rejection is improper and without merit.

Accordingly, the Examiner's reliance on Cohen, Prystowsky, and Altman fails to establish prima facie obviousness of dependent claims 15 and 16. Dependent claims 15 and 16 are also allowable at least by virtue of their dependence from allowable base claim 1. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### Rejection of Claim 28 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claim 28 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Smits</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

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A *prima facie* case of obviousness has not been established because, among other things, neither <u>Cohen</u> nor <u>Smits</u>, nor their combination, teaches or suggests each and every element of Applicant's claims. Specifically, <u>Cohen</u> and <u>Smits</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claim 24, from which claim 28 depends.

Applicant has already demonstrated previously herein that <u>Cohen</u> does not teach or suggest all the elements of independent claim 24. In addition, the Examiner admitted that <u>Cohen</u> does not teach "providing an electrode in the coronary vasculature" (Office Action, p. 8).

The Examiner's allegation that <u>Smits</u> teaches an "electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field ... (Fig. 15)" (Office Action, p. 8), is <u>incorrect</u>, and fails to cure the deficiencies of <u>Cohen</u> already discussed. Rather, <u>Smits</u> places "an optional coronary sinus defibrillation lead 294 ... as close as possible to the left ventricle. ... Such a location is desirable to assure adequate current density in the left ventricular wall" (col. 10, ll. 38-62, emphasis added, and Fig. 15). Further, <u>Smits</u> also teaches "electrodes 230 and 232 are both mounted <u>on</u> the left ventricle roughly equidistant from the septum of the heart" (col. 9, lines 34-36, emphasis added, and Fig. 12A). <u>Smits</u> does not teach placing electrodes *in* the left ventricle. Therefore, the teachings of <u>Smits</u> do not constitute Applicant's claimed "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24).

Thus, even if <u>Smits</u> were combined with <u>Cohen</u> as the Examiner suggests, <u>Cohen</u> and <u>Smits</u> do not teach or suggest all elements recited in independent claim 24, and required by dependent claim 28. Therefore, the Examiner's application of <u>Smits</u> as an additional reference does not render obvious the recitations of Applicant's dependent claim 28.

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For at least these reasons, the Examiner's rejection is improper and without merit.

Accordingly, the Examiner's reliance on <u>Cohen</u> and <u>Smits</u> fails to establish *prima facie*obviousness of dependent claim 28. Dependent claim 28 is also allowable at least by virtue of its dependence from allowable base claim 24. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### Rejection of Claims 34, 38, 39, 45-47, 51, and 52 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claims 34, 38, 39, 45-47, 51, and 52 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Smits</u>, and further in view of <u>Altman</u>.

Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

A *prima facie* case of obviousness has not been established because, among other things, none of <u>Cohen</u>, <u>Smits</u>, <u>Altman</u>, or their combination, teaches or suggests each and every element of Applicant's claims. Specifically, <u>Cohen</u>, <u>Smits</u>, and <u>Altman</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claims 24, 41, 46, and 51, from which claims 34, 38, 39, 45, 47, and 52 respectively depend.

First, Applicant has already demonstrated previously that <u>Cohen</u> and <u>Smits</u> do not teach or suggest "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24). In addition, the Examiner's application of <u>Altman</u>, for its "septal electrode using a helical wire" (Office Action, p. 9), fails to cure the deficiencies of <u>Cohen</u> and <u>Smits</u> already discussed. That is, <u>Altman</u> also fails to teach or suggest at least the claimed "stimulating the left ventricle of the heart at a plurality of locations in the left ventricle" (independent claim 24). Similarly, <u>Cohen</u>, <u>Smits</u>, and <u>Altman</u> do not teach or suggest "stimulating contraction at a plurality of locations in the left ventricle in response to the one or

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more control signals" (independent claim 41). Moreover, <u>Cohen</u>, <u>Smits</u>, and <u>Altman</u> do not teach or suggest "applying a second electrical signal to a second electrode implanted in the left ventricle" (independent claim 51).

Thus, even if <u>Altman</u> were combined with <u>Cohen</u> and <u>Smits</u> as the Examiner suggests, <u>Cohen, Smits</u>, and <u>Altman</u> do not teach or suggest all elements recited in independent claims 24, 41, 46, and 51, and required by dependent claims 34, 38, 39, 45, 47, and 52. Therefore, the Examiner's application of <u>Smits</u> and <u>Altman</u> as additional references to <u>Cohen</u> does not render obvious the recitations of Applicant's claims 34, 38, 39, 45-47, 51, and 52.

For at least these reasons, the Examiner's rejection is improper and without merit. The Examiner's reliance on Cohen, Smits, and Altman fails to establish *prima facie* obviousness of claims 34, 38, 39, 45-47, 51, and 52. Dependent claims 34, 38, 39, 45, 47, and 52 are also allowable at least by virtue of their respective dependence from allowable base claim 24, 41, 46, or 51. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### Rejection of Claims 48-50, 53, and 54 under 35 U.S.C. § 103(a):

Applicant traverses the rejection of claims 48-50, 53, and 54 under 35 U.S.C. § 103(a) as being unpatentable over <u>Cohen</u> in view of <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u>. Applicant respectfully disagrees with the Examiner's arguments and conclusions. A *prima facie* case of obviousness has not been established.

A *prima facie* case of obviousness has not been established because, among other things, none of <u>Cohen</u>, <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u>, or their combination, teaches or suggests each and every element of Applicant's claims. Specifically, <u>Cohen</u>, <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u>, taken alone or in combination, do not teach or suggest each and every element of Applicant's independent claims 48 and 51, from which claims 49, 50, 53, and 54 respectively depend.

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First, Applicant has already demonstrated previously, via a similar element in independent claim 24, that <u>Cohen</u> and <u>Prystowsky</u> do not teach or suggest "selectively applying a voltage sufficient to stimulate contraction to at least a second electrode implanted in the left ventricle" (independent claim 48). Likewise, the cited references do not teach or suggest "applying a first electrical signal to a first electrode implanted in the interventricular septum of the heart; and applying a second electrical signal to a second electrode implanted in the left ventricle" (independent claim 51).

Second, the Examiner's repeated allegation that <u>Smits</u> teaches an "electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field ..." (Office Action, pp. 9-10), is <u>incorrect</u>, for the reasons presented previously herein. That is, <u>Smits</u> does not teach or suggest placing electrodes *in* the left ventricle, as required by independent claims 48 and 51.

Third, the Examiner's repeated application of <u>Altman</u>, however, for its "septal electrode using a helical wire" (Office Action, p. 10), fails to cure the deficiencies of the other references already discussed. That is, <u>Altman</u> does not teach or suggest placing electrodes *in* the left ventricle, as required by independent claims 48 and 51.

Thus, even if <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u> were combined with <u>Cohen</u> as the Examiner suggests, <u>Cohen</u>, <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u> do not teach or suggest all elements recited in independent claims 48 and 51, and required by dependent claims 49, 50, 53, and 54.

Therefore, the Examiner's application of <u>Smits</u>, <u>Altman</u>, and <u>Prystowsky</u> as additional references to <u>Cohen</u> does not render obvious the recitations of Applicant's claims 48-50, 53, and 54.

For at least these reasons, the Examiner's rejection is improper and without merit. The Examiner's reliance on Cohen, Smits, Altman, and Prystowsky fails to establish prima facie

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obviousness of claims 48-50, 53, and 54. Dependent claims 49, 50, 53, and 54 are also allowable at least by virtue of their respective dependence from allowable base claim 48 or 51. The improper 35 U.S.C. § 103(a) rejection should be withdrawn.

### **Conclusion:**

In view of the foregoing, Applicant requests reconsideration of the application and withdrawal of the rejections. Pending claims 1-54 are in condition for allowance, and Applicant requests a favorable action.

If there are any remaining issues or misunderstandings, Applicant requests the Examiner telephone the undersigned representative to discuss them.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 11, 2006

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